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Attorney Docket: 763-29

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

APPLICANT: Yoshio Jo et al. **EXAMINER:** Oh, Simon J.
SERIAL NO.: 10/069,561 **GROUP ART UNIT:** 1618
FILED: October 22, 2001 **DATED:** August 8, 2005
FOR: **SOLUBLE TRAUMA-HEALING HEMOSTATIC CELLULOSE
CONTAINING COAGULATION PROTEIN AND METHOD
OF PREPARATION THEREOF**

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

Pursuant to 37 C.F.R. §41.41, please enter and consider the following Reply Brief
the Examiner's Answer mailed June 6, 2005 by the Patent and Trademark Office in the
above-identified application. Reference will be made to the various passages in the
Examiner's Answer. The following points I-VII will be explicitly addressed:

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this that this paper (along with any paper referred to as being attached or
enclosed) is being deposited with the United States Postal Service as first class mail, postpaid in an envelope
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Dated: August 8, 2005


George M. Kaplan

I. THE COMBINATION OF REFERENCES FASHIONED IN THE FINAL REJECTION

FAILS TO ESTABLISH A CASE OF *PRIMA FACIE* OBVIOUSNESS

In the first full paragraph on page 7 of the Examiner's Answer, it is stated:

In this case, the breadth of claims, as characterized by the use of the transitional phrase "comprising" permits a broad approach to the instantly claimed subject matter by the examiner. The deciding factor in this case is that the prior art references broadly deal with the same filed of endeavor to solve the same problem, that is, wound healing [emphasis added].

However, Columbo et al. citation fails to address wound-healing benefit. In the second paragraph on page 7 of his Answer, the Examiner alleges "the Columbo et al. patent discloses such methods of production." However, Columbo et al. merely relate to etherification of cellulose fibers ultimately used in products such as sanitary towels or napkins, bandages, tampons, etc. (column 7, lines 1-2); there is no suggestion in this reference of utilizing the fibers for wound healing effect. In this regard, some suggestion or motivation to combine or modify the reference teachings must exist to establish a *prima facie* case of obviousness as enunciated in M.P.E.P. §2142. Accordingly, the combination of references fashioned in the final rejection fails to establish a case of *prima facie* obviousness.

II. THERE IS NO MOTIVATION TO COMBINE EP '869 WITH COLUMBO ET AL., EDWARDSON ET AL AND SUGITACHI ET AL AS IN THE FINAL REJECTION

In the first full paragraph on page 9 of his Answer, the Examiner asserts

... it is the position of the examiner that one of ordinary skill in the art would find the instantly claimed invention obvious in view of the collective disclosure of the prior art, would have a clear motivation to combine the references, and would have a reasonable expectation of success in doing so.

However, Board of Patent Appeals and Interferences in the decision *Ex parte Humphreys*, 24 USPQ2d 1255 (BPAI 1992) explicitly stated:

The examiner's rejection is not specific as to how one of ordinary skill in the art would have found it obvious to practice any specific method within the scope of these claims as of the filing date of this application... 24 USPQ2d at 1262 [emphasis added].

It follows from the *Humphreys* decision *supra*, if the Examiner does not provide specific reasons to support the obviousness rejection, the Examiner would fail to establish a *prima face* case of obviousness.

In the second paragraph on page 9 of his Answer, the Examiner merely alleges a clear link between the four prior art references has been established by showing the references are all in the field of the same general problem, that of wound healing. As explained above, there is no suggestion in Columbo et al reference of utilizing the fibers for wound healing effect. Thus, the Examiner has presented no specific reasons how one of ordinary skill in the art would found it obvious to construct the claimed invention in light of these four references.

In the present instance, EP '869 fails to disclose a hemostatic fiber; Columbo et al merely relate to etherification of cellulose fibers ultimately used in products such as sanitary towels or napkins, bandages, tampons, etc., there being no suggestion of providing wound healing benefit; Edwardson et al just contain a general disclosure a thrombin-like enzyme can be immobilized upon a support such as cellulose or derivatives, there being no explicit teaching of preparing an etherified cellulose fiber with the coagulation protein combination as recited in the claimed invention; and Sugitachi et al merely disclose fixing blood coagulation factor XIII to a variety of structures such as sutures, pads, bandages, etc.

Thus, there is no explicit suggestion in Sugitachi et al, or any of the other references, of preparing the claimed cellulose fiber with all three coagulation proteins in combination. The structures of Columbo et al and Sugitachi et al are not designed for dissolution as claimed. That is why Applicants have pointed out the disclosures of the various references show products such as bandages, pads, and sutures, as questioned by the Examiner on page 6 of the Final Office Action. The Examiner asserts bandages, pads and sutures are presumably used for wound healing benefit. However, feminine hygiene products are not “presumably” used to treat wounds.

Therefore, it is quite clear the only motivation of preparing a soluble, trauma-healing hemostatic fiber in the fashion of the claimed invention is found in the present application.

III. THE CLAIMED INVENTION IS NOT INHERENTLY SHOWN BY THE PRIOR ART

In the third paragraph on page 9 of his Answer, the Examiner alleges it stands to reason that such cellulose material would exhibit the same attributes as claimed by the appellant, such as solubility and rapid dissolution.” As pointed out *supra*, Columbo et al and Sugitachi et al teach away from providing a water-soluble composition with Columbo et al explicitly teaching a water-insoluble cellulose fiber. Accordingly, if anything, the combination of art fashioned by the Examiner teaches away from the presently claimed invention. *Gillete Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 USPQ2d, 1923, 1927 (Fed. Cir. 1990).

IV. THE REFERENCES MUST BE CONSIDERED IN THEIR ENTIRETY

At the top of page 8 of his Answer, the Examiner dismisses Appellants' argument on the Examiner's need to combine a large number of references to fashion the alleged rejection and asserts, at the bottom of page 6 of his Answer, Appellants cannot individually attack references where a rejection is based upon a combination of the references.

However, the totality of the references' teachings must be considered. *W. L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-1, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Appellants have considered the teachings of the applied references in their entireties. Furthermore, combining a large number of references has been shown to "skirt all around" the claimed invention and fail to establish obviousness. *Hybritech, Inc., v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 USPQ 81, 83 (Fed. Cir. 1986).

V. THE EXAMINER IMPROPERLY IGNORES THE EVIDENCE OF RECORD

In paragraph (E) on pages 9-10 of his Answer, the Examiner simply dismisses the test results and arguments containing in the Declaration under 35 U.S.C. §1.132 from Mr. Jo. More specifically, the Examiner does not dispute the test results, but simply asserts the Examiner's motivation for combining the art to fashion the rejection is simply based upon wound-healing benefit, and not improved performance of fibrinomer absorptivity, platelet agglutination, or adhered cell count. However, it is well-settled in the law, evidence of such improved performance can indeed be used to rebut a *prima facie* case of obviousness. *In re*

Mayne, 104 F.3d 1339, 1343, 41 USPQ2d 1451, 1455 (Fed. Cir. 1997); *In re Soni*, 54 F.3d 746, 749, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995).

The Examiner fails to provide any evidence of his own attacking the evidence of record, but improperly dismisses the evidence of record as simply “unpersuasive.”

VI. RELYING UPON THE PATENT APPLICATION TO FASHION A HINDSIGHT REJECTION IS IMPROPER

In paragraph (C) at the bottom of page 8 of his Answer, the Examiner continues to assert

it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning.

Furthermore, the Examiner asserts on page 10 of his Answer

As explained above, as the prior art has broadly disclosed the instantly claimed invention, having the same structure and the same components, it would follow that the composition arising from this collective disclosure would also have the same properties as that claimed by the appellant, such as fibrinomer absorptivity, improved platelet agglutination, and improved adhered cell count [emphasis added].


However, as acknowledged by the Examiner, the applied art fails to teach or suggest these improvements. The only evidence of these improvements is found in the present application which cannot be used to fashion a hindsight rejection of the claimed invention. The patent application cannot be used as a guide through the maze of prior art references to combine the right references in the right fashion to teach the claimed invention. *Grain Processing Corp. v. American Maize-Products Corp.*, 840 F.2d 902, 907, 5 USPQ2d 1885, 1888 (Fed. Cir. 1988). The patent application cannot be used as a template to fill in the gaps or deficiencies in the prior art teachings. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991); and *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).

VII. PATENTABILITY OF CLAIMS 67-74 HAVE BEEN EXPLICITLY ADDRESSED IN APPELLANTS' BRIEF

It is asserted by the Examiner on page 12 of his Answer, patentability of Claims 67-74 have not been addressed in Appellants' Brief. The recitations of Claims 67-74 are found in the evidence of record in the present application and were explicitly addressed in paragraph 7(E) of Appellants' Brief.

Separately, an amendment making formal revisions in Claims 69 and 70 is being simultaneously submitted herewith.

Respectfully submitted,


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